



Patent Attorney's Docket No. <u>008439-029</u>

IN THE UNITED STATES PATENT AND TRADEMARK OFFICE

In re Reissue Application of U.S. Patent No. 5,681,932)
Brian W. GRINNELL) Group Art Unit: Unassigned
Application No.: Unassigned) Examiner: Unassigned
Filed: August 26, 1999)
For: METHOD OF USING EUKARYOTIC EXPRESSION VECTORS COMPRISING THE BK VIRUS ENHANCER))))

CONSENT OF ASSIGNEE OF ENTIRE INTEREST

Assistant Commissioner for Patents Washington, D.C. 20231

Sir:

Eli Lilly and Company, the sole owner of the entire right, title and interest in U.S. Patent No. 5,681,932, by virtue of the Assignment recorded in the U.S. Patent and Trademark Office at Reel 7842, Frame 647, hereby consents to the application for reissue of U.S. Patent No. 5,681,932.

Respectfully submitted,

ELI LILLY AND COMPANY

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Name: Robert A. Conrad

Title: Assistant General Patent Counsel

Lilly Corporate Center Indianapolis, Indiana 46285 (317) 276-2000

Date: Cuy \$ 24,1999



Applicant: Brian W. GRINNELL
Reissue Application of Patent No.: 5,681,932 Issued: October 28, 1997
For: METHOD OF USING EUKARYOTIC EXPRESSION VECTORS COMPRISING THE BK VIRUS ENHANCER
ELI LILLY AND COMPANY (Name of Assignee)
(Name of Assignee)
a corporation (Type of Assignee, e.g., corporation, partnership, university, government agency, etc.)
certifies that it is the assignee of the patent application identified above by virtue of either:
A. [X] An assignment from the inventor(s) of the patent application identified above. The assignment was recorded in the Patent and Trademark Office at Reel 7842, Frame 647, or for which a copy thereof is attached.
OR
B. [] A chain of title from the inventor(s), of the patent application identified above, to the current assignee as shown below:
1. From: To: To: The document was recorded in the Patent and Trademark Office at Reel, Frame, or for which a copy thereof is attached.
2. From: To: To: The document was recorded in the Patent and Trademark Office at Reel, Frame, or for which a copy thereof is attached.
3. From: To: To: The document was recorded in the Patent and Trademark Office at Reel, Frame, or for which a copy thereof is attached.
[] Additional documents in the chain of title are listed on a supplemental sheet.
[] Copies of assignments or other documents in the chain of title are attached.
The undersigned (whose title is supplied below) is empowered to act on behalf of the assignee.
I hereby declare that all statements made herein of my own knowledge are true, and that all statements made on information and belief believed to be true; and further, that these statements are made with the knowledge that willful false statements, and the like so made, a punishable by fine or imprisonment, or both, under Section 1001, Title 18 of the United States Code, and that such willful false statements may jeopardize the validity of the application or any patent issuing thereon.
Date : Ceynt 24, 1999
Name : Robert A. Conrad
Title : Assistant General Patent Counsel
Signature - PIGO





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IN THE UNITED STATES PATENT AND TRADEMARK OFFICE

In re Reissue Application of U.S. Patent No. 5,681,932)
Brian W. GRINNELL) Group Art Unit: Unassigned
Application No.: Unassigned) Examiner: Unassigned
Filed: August 26, 1999)
For: METHOD OF USING EUKARYOTIC EXPRESSION VECTORS COMPRISING THE BK VIRUS ENHANCER)))

DECLARATION UNDER 37 C.F.R. §1.175(a)

Assistant Commissioner for Patents Washington, D.C. 20231

Sir:

I, Brian W. Grinnell, the undersigned Petitioner, hereby declares that I reside at 3625 East 71st Street, Indianapolis, Indiana 46220, and that I am a citizen of the United States. I believe that I am the first, original and sole inventor of the subject matter which is claimed in this application for reissue and for which reissue of the original Letters Patent, U.S. Patent No. 5,681,932, on the invention entitled "METHOD OF USING EUKARYOTIC EXPRESSION VECTORS COMPRISING THE BK VIRUS" is sought. I do not believe that the invention was ever known or used before my invention thereof was made.

The entire right, title and interest in and to United States Letters Patent No.

5,681,932, granted October 28, 1997, and entitled "METHOD OF USING EUKARYOTIC

EXPRESSION VECTORS COMPRISING THE BK VIRUS ENHANCER" is vested in Eli Lilly

and Company, a corporation existing under the laws of the State of Indiana, having a place of business at Lilly Corporate Center, Indianapolis, Indiana 46285.

Petitioner further declares the following:

Petitioner verily believes United States Letters Patent No. 5,681,932 may be at least partly inoperative for the reason that Petitioner claimed less than Petitioner had the right to claim in the patent.

The first set of claims to be added defines a human protein C having a glycosylation pattern containing N-acetylgalactosamine (GalNAc). *See*, claims 5-28 and 33. It was error for Petitioner to omit a set of claims defining human protein C in this manner in the Patent. Support for claims of this scope, e.g., claims 5-28 and 33, may be found at the very least at from column 16, line 59 to column 17, line 64, including Table 2, and at from column 68, line 65 to column 69, line 23. It was error for Petitioner to omit such claims in the Patent.

The second set of claims to be added defines a human protein C having specified amounts of fucose and N-acetylgalactosamine per mole of human protein C. *See*, claims 29-32. Support for claims of this scope, e.g., claims 29-32, may be found at the very least at from column 16, line 59 to column 17, line 20, in particular Table 2. It was error for Petitioner to omit such claims in the Patent.

The third set of claims to be added defines a human protein C having about 50% less sialic acid than human plasma protein C. See, claims 34 and 35. Support for claims of this

scope, e.g., claims 34 and 35, may be found at the very least at Table 2, column 17, lines 1-14. It was error for Petitioner to omit such claims in the Patent.

The fourth set of claims to be added define a human protein C having increased anticoagulant and functional activities as compared to plasma human protein C. *See*, claims 36 and 37. Support for claims of this scope, e.g., claims 36 and 37, may be found at the very least at from column 16, lines 48-67, and at column 17, lines 55-57. It was error for Petitioner to omit such claims in the Patent.

The fifth set of claims to be added defines a human protein C having a glycosylation pattern containing N-acetylgalactosamine (GalNAc) as a product-by-process claim. *See,* claims 38-45 Support for claims of this scope, e.g., claims 38-45, may be found at the very least at from column 15, line 61 to column 17, line 64, and at from column 68, line 65 to column 69, line 23. It was error for Petitioner to omit such claims in the Patent.

In addition, new claim 46 defines a recombinant γ-carboxylated protein by the process used to produce the protein. Support for this claim may be found at the very least at column 15, lines 36-60. It was error for Petitioner to omit a claim of this scope in the Patent.

Further, claim 47 defines a recombinant glycoprotein produced by a host cell selected from the group consisting of AV12 cells and human embryonic kidney 293 cells.

Support for this claim may be found at the very least at column 15, line 30 to column 16, line 37.

It was error for Petitioner to omit a claim of this scope.

Claims 48-50 further define the recombinant human protein C of claim 1 by the process used to produce it. Support for these claims may be found at the very least at column 15, line 35 to column 16, line 37. It was error for Petitioner to omit a claim of this scope in the Patent.

Since this reissue is being filed within two years of the issue date of the aboveidentified patent, broader claims than those in the issued patent are permissible.

This application for reissue of the original Letters Patent addresses the aboveidentified errors in Petitioner claiming less than Petitioner had the right to claim in the patent by adding new claims as identified *supra*. All of the errors being corrected in the above-identified reissue application occurred without any deceptive intention on Petitioner's part.

Petitioner has reviewed and understands the contents of the specification, including the claims, as presented in the accompanying application for reissue.

Petitioner acknowledges the duty to disclose information of which Petitioner is aware and which is material to the examination of this application for reissue.

The undersigned hereby declares further that all statements made herein of his own knowledge are true, and that all statements made on information and belief are believed to be true; and further that these statements were made with the knowledge that willful false statements and the like so made are punishable by fine or imprisonment, or both, under section



1001 of title 18 of the United States Code, and that such willful false statements may jeopardize the validity of the application or any patent issuing thereon.

Respectfully submitted,

By:

Brian W. Grinnel

ELI LILLY AND COMPANY Lilly Corporate Center Indianapolis, Indiana 46285 (317) 276-2000

Date: August 23, 1999

IN THE UNITED STATES PATENT AND TRADEMARK OFFICE

In re Reissue Application of U.S. Patent No. 5,681,932)
Brian W. GRINNELL) Group Art Unit: Unassigned
Application No.: Unassigned) Examiner: Unassigned
Filed: August 26, 1999)
For: METHOD OF USING EUKARYOTIC)
EXPRESSION VECTORS)
COMPRISING THE BK VIRUS	í
ENHANCER	Ś
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POWER OF ATTORNEY BY ASSIGNEE OF ENTIRE INTEREST

Assistant Commissioner for Patents Washington, D.C. 20231

Sir:

As Assignee of the entire interest in the above-identified application, R. Danny Huntington, Registration No. 27, 903, Donna M. Meuth, Registration No. 36,607, Brian P. Barrett, Registration No. 39,597, Michael T. Bates, Registration No. 34,121, Roger S. Benjamin, Registration No. 27,025, William R. Boudreaux, Registration No. 35,796, Steven P. Caltrider, Registration No. 36,467, Paul R. Cantrell, Registration No. 36,470, Daniel W. Collins, Registration No. 31,912, Robert A. Conrad, Registration No. 32,089, Anne I. Craig, Registration No. 32,976, Paul R. Darkes, Registration No. 33,862, Stephen G. Davis, Registration No. 39,652, John C. Demeter, Registration No. 30,167, John H. Engelmann, Registration No. 28,075, Paul J. Gaylo, Registration No. 36,808, Edward P. Gray, Registration No. 30,638, Amy E. Hamilton, Registration No. 33,894, Frederick D. Hunter, Registration No. 26,915, Thomas E. Jackson, Registration No. 33,064, Charles Joyner, Registration No. 30,466, James J. Kelley, Registration No. 41,888, Paul C. Kimball, Registration No. 34,641, Paul J. Koivuniemi, Registration No.

Application No. <u>Unassigned</u> Attorney's Docket No. <u>008439-029</u>

31,533, Robert E. Lee, Registration No. 27,919, James P. Leeds, Registration No. 35,241, Nelsen L. Lentz, Registration No. 38,537, Ronald S. Maciak, Registration No. 35,262, Janet T. McClain, Registration No. 36,863, Scott A. McNeil, Registration No. 37,185, Arlene K. Musser, Registration No. 37,895, Douglas K. Norman, Registration No. 33,267, Arleen Palmberg, Registration No. 40,422, Raymond S. Parker, III, Registration No. 34,893, Thomas G. Plant, Registration No. 35,784, James J. Sales, Registration No. 33,773, Michael J. Sayles, Registration No. 32,295, David M. Stemerick, Registration No. 40,187, Mark J. Stewart, Registration No. P43,936, Robert D. Titus, Registration No. 40,206, Guy K. Townsend, Registration No. 34,033, Barbara Twardzik, Registration No. 36,386, MaCharri Vorndran-Jones, Registration No. 39,872 and Lawrence T. Welch, Registration No. 29,487 are hereby appointed to prosecute and transact all business in the U.S. Patent and Trademark Office connected with the above-identified application.

The Assignee has reviewed documentary evidence of the chain of title from the original owner to the Assignee recorded in the U.S. Patent and Trademark Office at Reel 7842, Frame 647, and certifies that to the best of its knowledge and belief it is the owner of the entire right, title and interest in and to the above-identified application.

Application No. <u>Unassigned</u> Attorney's Docket No. <u>008439-029</u>

Correspondence and telephone calls regarding this reissue application should be

directed to:

R. Danny Huntington, Esq.
BURNS, DOANE, SWECKER & MATHIS, L.L.P.
P.O. Box 1404
Alexandria, Virginia 22313-1404
(703) 836-6620
(703) 836-2021 fax

Respectfully submitted,

ELI LILLY AND COMPANY

Name: Robert A. Conrad

Title: Assistant General Patent Counsel

Lilly Corporate Center Indianapolis, Indiana 46285 (317) 276-2000

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IN THE UNITED STATES PATENT AND TRADEMARK OFFICE

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) Group Art Unit: Unassigned
) Examiner: Unassigned
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OFFER TO SURRENDER ORIGINAL LETTERS PATENT

Assistant Commissioner for Patents Washington, D.C. 20231

Sir:

Eli Lilly and Company, the sole owner of the entire right, title and interest in U.S. Patent No. 5,681,932, by virtue of the Assignment recorded in the U.S. Patent and Trademark Office at Reel 7842, Frame 647, hereby offers to surrender U.S. Patent No. 5,681,932, conditional upon the Reissue of said Letters Patent.

Respectfully submitted,

ELI LILLY AND COMPANY

Name: Robert A. Conrad

Title: Assistant General Patent Counsel

Lilly Corporate Center Indianapolis, Indiana 46285 (317) 276-2000

Date: (200

-5724,1229